DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

OCT - 5 2000

WARNING LETTER

VIA FEDERAL EXPRESS
VIA FACSIMILE

David J. Narins, M.D.
The Dermatology Surgery and Laser Center
222 Westchester Avenue
White Plains, New York 10604

Re: Adatomed Silicone Oil OP5000, P910071

Dear Dr. Narins:

The Food and Drug Administration (FDA) has reviewed your web site at the internet address: http://www.narins.com for the Adatomed Silicone Oil OP5000 (Adatomed Silicone). Adatomed Silicone is manufactured by Bausch & Lomb, is used in your practice, and is a device as defined within the meaning of section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

On November 4, 1994, FDA approved Adatomed Silicone through the Premarket Approval process (PMA) pursuant to section 515(d)(1)(B)(ii) of the Act. Additionally, to ensure the safe and effective use of the device, FDA also determined that Adatomed Silicone is restricted within the meaning of section 520(e) of the Act in that the sale and distribution must not violate sections 502(q) and 502(r) of the Act. These sections of the Act state, respectively, that the advertising must not be false or misleading in any particular; and that all advertising or other descriptive printed matter issued by a manufacturer or distributor, must include the relevant warnings, precautions, side effects, and contraindications for the device.

Adatomed Silicone is indicated for use as a prolonged retinal tamponade in selected cases of complicated retinal detachments where other interventions are not appropriate for patient management. Complicated retinal detachments or recurrent retinal detachments occur most commonly in eyes with proliferative vitroretinopathy (PVR), proliferative diabetic retinopathy (PDR), cytomegalovirus (CMV) retinitis, giant tears, and following perforating injuries. Adatomed Silicone is also indicated for primary use in detachments due to Acquired Immune Deficiency Syndrome (AIDS)-related CMV retinitis, and other viral infections.

Although physicians may use a legally marketed medical device to treat patients for any intended use that he/she desires within the bounds of his/her state licensing requirements, a licensed practitioner may not promote that medical device for use(s) that have not been approved by FDA.

Your web site promotes Adatomed Silicone as a treatment for skin defects such as wrinkles or scars, neither of which have been approved by FDA. Representative statements and phrases made on your web site include the following:

- Silicone has been used to correct skin defects for more than 30 years. After several years of not being used amidst a lot of media attention, it has now been FDA "*approved as Adatosil for use in the eye. We are using it to correct skin defects such as wrinkles and scars in an off-label use.*" Many of our patients have been waiting and hoping for its return as it is a more permanent filling substance that looks very natural

- Silicone has been approved by the FDA for use in the eye. We are now able to use this permanent filling substance to treat wrinkles, folds, scars, and depressions

- Benefits of Silicone…More permanent; used for years; no allergies, no testing; no surgery necessary; natural more youthful appearance; amazing results when used with Botox

Your promotion of the Adatomed Silicone for the treatment of skin defects such as wrinkles and/or scars, or as a permanent filling substance to treat skin folds or depressions, is a violation of the law. In legal terms, the Adatomed Silicone is adulterated within the meaning of section 501(f)(1)(B) of the Act in that it is a Class III device under section 513(f), and does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a), or an approved application for Investigational Device Exemption (IDE) under section 520(g).

The Adatomed Silicone is also misbranded within the meaning of section 502(o) of the Act, in that the device was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 510(k), was not included in a list required by section 510(j), and a notice or other information respecting the device was not provided to the FDA as required by section 510(k).

This letter is not intended to be an all-inclusive list of deficiencies associated with the use of the Adatomed Silicone. It is your responsibility to ensure adherence to each requirement of the Act and Federal regulations. The specific violations noted in this letter may represent practices used in other promotion or advertising materials used by your center and/or medical practice. You are responsible for investigating and reviewing these materials to assure compliance with applicable regulations.

You should take prompt action to correct these violations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office, in writing, within 15 working days of receipt of this letter, outlining the specific steps you have taken to correct the cited violations. Your response should also include all steps being taken to address misleading information currently in the market place and actions to prevent similar violations in the future. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Mr. Steven E. Budabin, Consumer Safety Officer, Promotion and Advertising Policy Staff (HFZ-302), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850.

A copy of this letter is being sent to FDA's New York District Office. Please send a copy of your response to the District Director, Food and Drug Administration, New York District Office (HFR-NE100), 850 Third Avenue, Brooklyn, New York 11232.

Sincerely yours,

Byron J. Tart for

Larry D. Spears
Acting Director
Office of Compliance
Center for Devices and
Radiological Health